TECHNICAL SERVICES MONTHLY REPORT

Nov 2022 to Feb 2023

TSD Approach

- **Service Capabilities**
  - On time deliverables
  - Quality Work
- **Trouble Shooting**
  - Unit Process
  - Unit Operations
- **Continuous Improvements**
  - Solvent
  - Yield
  - Capacity
- **New Products**
  - Eqp. Mapping
  - Trail & Validation
  - Execution

Ongoing Projects

- Capacity Enhancement
- New Products
- Technical Support
- New Proposals

Capacity Enhancement

Product Name:
Pregabalin

Stage Code :

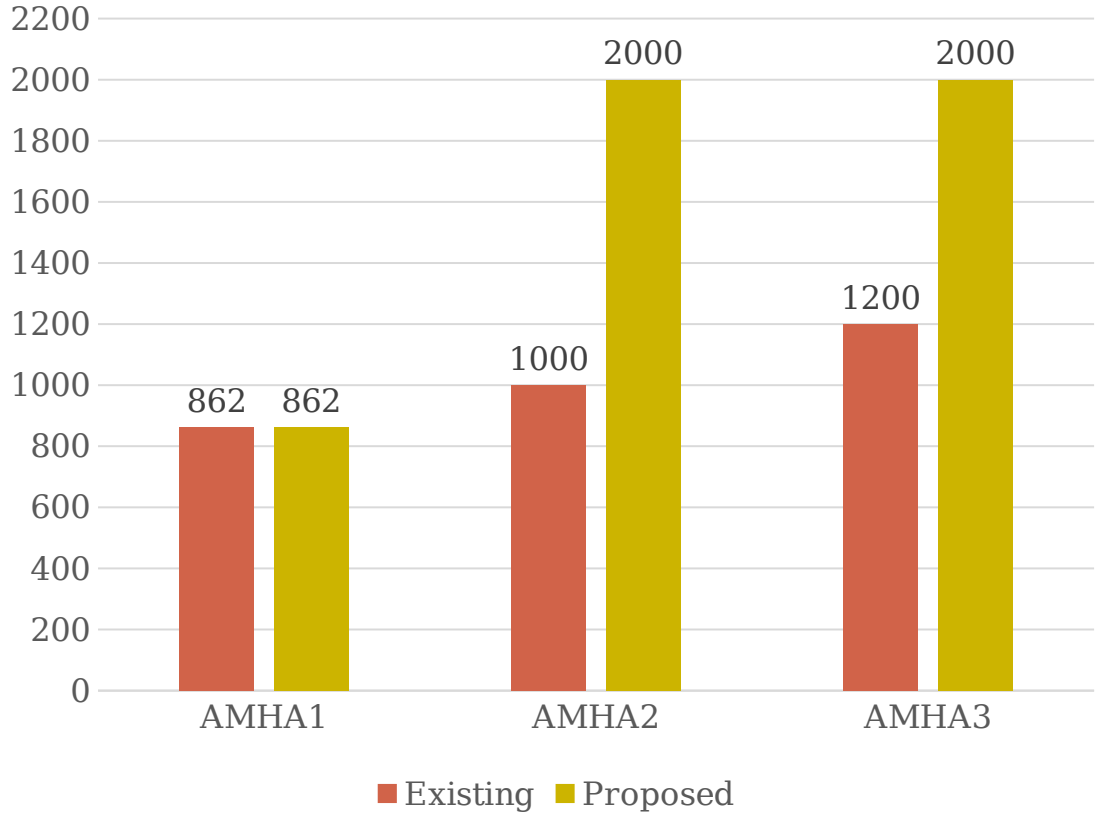
AMHA1: Additional streams included,
AMHA2: Scale-up from 1000 Kg in A-Block to 2000 Kg in C-Block &
AMHA3: Additional streams included.

Block: A, B & C.

Existing : 18 to 20 TPM.

Proposed : 28 to 30 TPM.

AMHA1		AMHA2		AMHA3	
Existing	Proposed	Existing	Proposed	Existing	Proposed
862 kg	862 kg	1000 kg	2000 kg	1200 kg	2000 kg



Capacity Enhancement

Product Name: Atorvastatin Calcium

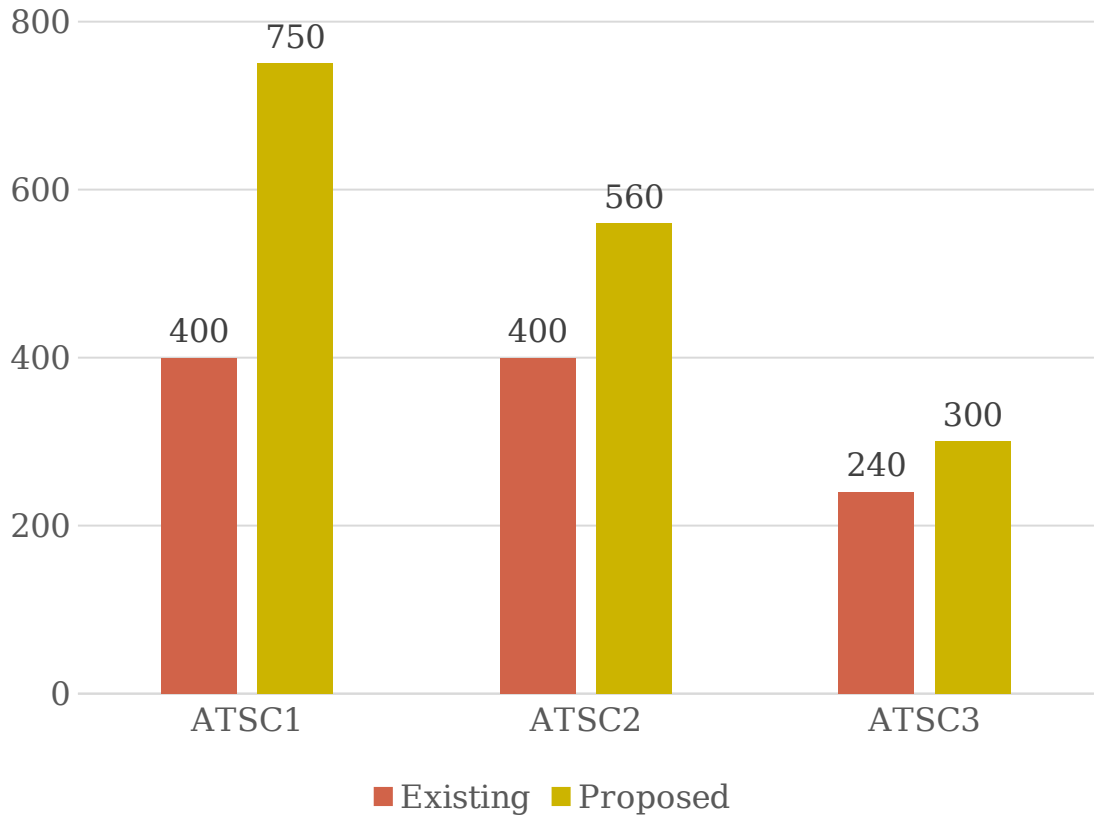
Stage Code : ATSC1, ATSC2 & ATSC3.

Block: B & E.

Existing : ~4.2 TPM.

Proposed : ~8.4 TPM.

ATSC1		ATSC2		ATSC3	
Existing	Proposed	Existing	Proposed	Existing	Proposed
400 kg	750 kg	400 kg	560 kg	240 kg	300 kg



Capacity Enhancement

Product Name: Rosuvastatin Calcium (RA)

Stage Code : RVST1 & RVST2.

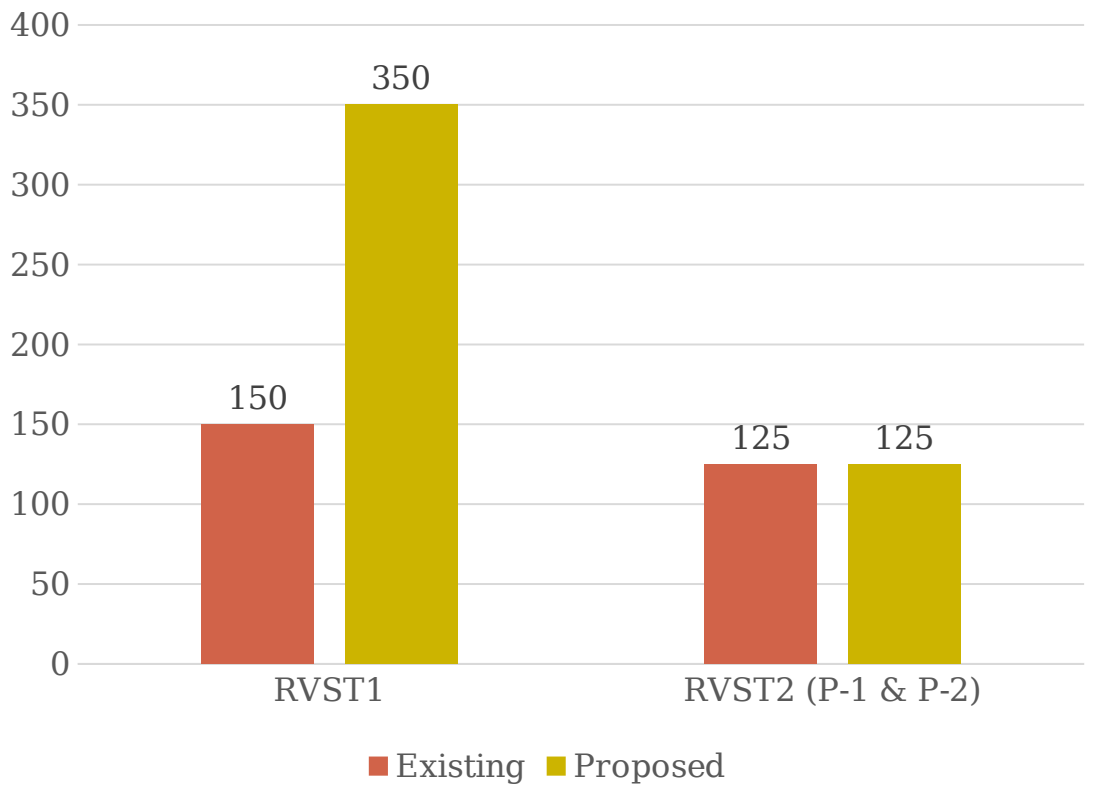
RVST2 Additional Clean room added in F-Block along with existing in E-Block

Block: E & B.

Existing : 2.0 TPM.

Proposed : 4.0 TPM.

RVST1		RVST2	
Existing	Proposed	Existing Phase-I	Proposed Phase-I & II
150 kg	350 kg	125 kg	125 kg



Capacity Enhancement

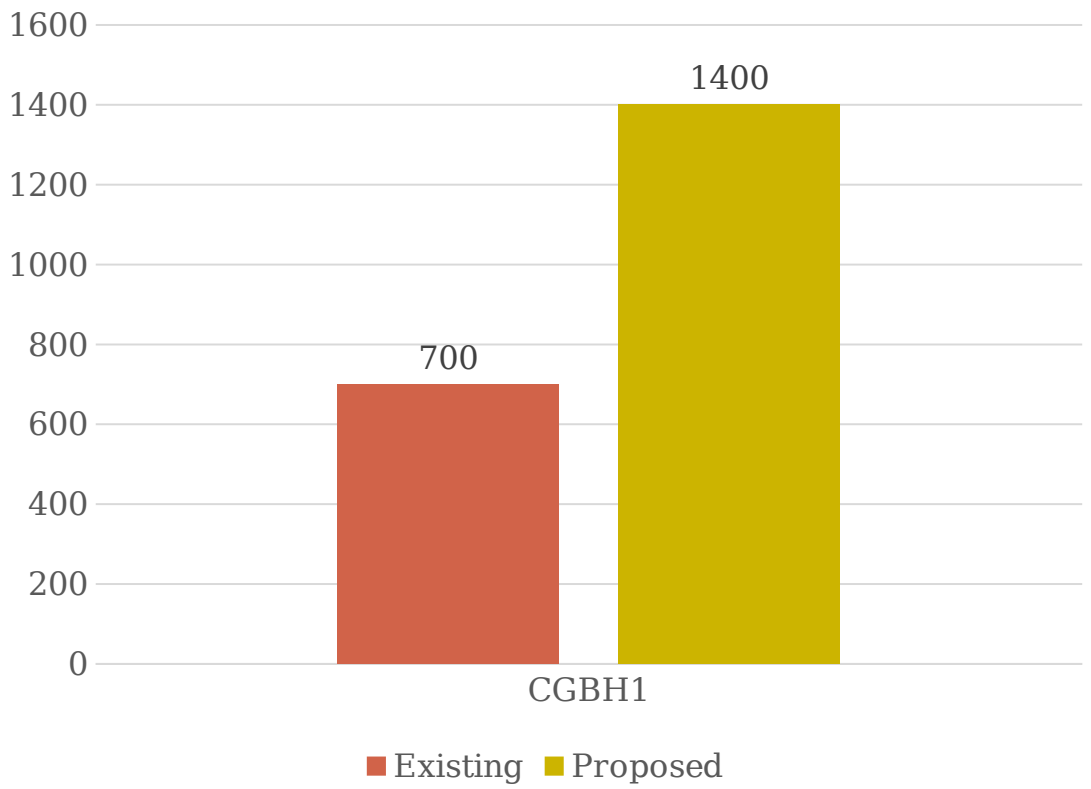
Product Name:
Clopidogrel Bisulfate

Stage Code : CGBH1 scale-up from 700 Kg in B-Block to 1400 Kg in C-Block.

Block: B & C.

Status: To be implemented after receiving Raw materials

CGBH1	
Existing	Proposed
700 kg	1400 kg



New Products

Sucralfate

Istradefylline

Voxelotor

SUCRALFATE

Stage	Trail / Validation	Start Date	End date	I/P (Kg)	O/P (Kg)	Yield Range (Kg)
SFTE1	T1	26-10-22	31-10-22	7.0	20.36	17.58 to 21.48
SFTE1	V1	19-11-22	23-11-22	7.4	23.2	18.59 to 22.71
SFTE1	V2	07-12-22	11-11-22	7.4	24.18	
SFTE1	V3	20-12-	25-12-	7.4	24.5	

Stage	Trail / Validation	Start Date	End date	I/P (Kg)	O/P (Kg)	Yield Range (Kg)
SFTE2	T1	15-12-22	21-01-23	20	34.55	31.80 to 38.8
SFTE2	V1	02-01-23	08-01-23	22	39.2	34.98 to 42.68
SFTE2	V2	11-01-23	17-01-23	22	35.2	
SFTE2	V3	18-01-23	24-01-23	22	37.1	

New Products

Sucralfate

Istradefylline

Voxelotor

MICRONIZATION DETAILS

Batch No	I/p (Kg)	O/p (Kg)	Top Sieved (Kg)	Loss Qty (Kg)	Samples Qty (Kg)
PSCFT0051222	14	11.2	1.2	1.28	0.32

Batch No	I/p (Kg)	O/p (Kg)	Top Sieved (Kg)	Loss Qty (Kg)	Samples Qty (Kg)
PSCFT0061222	12.9	11.39	0.23	1.055	0.195

New Products

Sucralfate

PSD as per Customer requirement
D90 NMT : 15(µm)

SSA NLT : 4.

Micronization three times trails done and meet the customer requirement.

MICRONIZATION DETAILS

Trail	D90 (µm)	D50 (µm)	D10 (µm)	SSA
Plain material	399	168	38.5	---
1st time Micronization	22.2	9.48	2.57	2.848
2nd Time Micronization	13.9	6.5	2.12	5.777
3rd Time Micronization	12	5.92	1.89	5.873

New Products

Sucralfate

Istradefylline

Voxelotor

ISTRADEFYLLINE

Stage	Trail / Validation	Start Date	End date	I/P (Kg)	O/P (Kg)	Yield Range (Kg)
IDLE1	T1	03-12-22	03-12-22	7.0	8.0	6.44 to 7.98
IDLE1	V1	20-12-22	23-12-22	7.5	7.69	6.90 to 8.5
IDLE1	V2	28-12-22	31-12-22	7.5	8.94	

Stage	Trail / Validation	Start Date	End date	I/P (Kg)	O/P (Kg)	Yield Range (Kg)
IDLE2	T1	27-01-23	01-02-23	7.50	8.64	7.95 to 9.75
IDLE2	V1 to	Batches planned to be execute				

Stage	Trail / Validation	Start Date	End date	I/P (Kg)	O/P (Kg)	Yield Range (Kg)
IDLE3	Technology Transfer pending.					
IDLE4						

New Products

Opicapone

Sucralfate

Istradefylline

Voxelotor

VOXELOTOR

Stage	Trail / Validation	Start Date	End date	I/P (Kg)	O/P (Kg)	Yield Range (Kg)
VOTR 1	T1	02-11-22	06-11-22	40	67.9	59.2 to 72.4
VOTR 1	V1	29-11-22	02-12-22	42	71.1	
VOTR 1	V2	08-12-22	12-12-22	42	72.1	62.16 to 76.02

Stage	Trail / Validation	Start Date	End date	I/P (Kg)	O/P (Kg)	Yield Range (Kg)
VOTR 2	T1	24-11-22	28-11-22	10	9.8	8.2 to 10.0
VOTR 2	T2	06-12-22	16-12-22	57	46.3	46.74 to 57
VOTR 2	RP	--	19-02-23	25.45	18.82	---
VOTR 2	V1	06-01-23	12-01-23	70	66.6	
VOTR 2	V2	13-01-23	22-01-23	70	66.0	57.4 to 70.0
VOTR		20-01-	29-01-			

New Products

Opicapone

Sucralfate

Istradefylline

Voxelotor

VOXELOTOR

Stage	Trail / Validation	Start Date	End date	I/P (Kg)	O/P (Kg)	Yield Range (Kg)
VOTR 3	T1	07-01-23	12-01-23	45	39.5	34.65 to 42.3
VOTR 3	RP	--	--	39.5	34.7	
VOTR 3	V1	23-02-23	U/ Process	63		48.51 to 59.22
VOTR 3	V2, V3	Batches scheduled for execution				

TECHNICAL SUPPORT

I-Block

- I-Block equipment's i.e., Filtration and Drying equipment's modified as per Mr. Vithal sir instruction.
- Accessories requirements finalized for G-Block & D-Blocks.

Creation

- 6.0 KL Hydrogenation Reactor facility created in B-Block for ATSC1 stage of Atorvastatin calcium and scale-up batches execution completed with Input 400 Kg, 600 Kg & 750 Kg.
- Azeotropic Set-up arranged for Oseltamivir Phosphate for water removal.
- Vacuum balancing set-up arranged to F/SSR/03 (4 KL) in F-Block for Rosuvastatin Calcium Pharma Stage.

New Proposal

- In PD LAB experiments conducted for Hydrolysis Reaction to avoid frothing and increase batch size in PREGABALIN (AMHA1) in heating condition. One small batch to be execute in plant.
- ANFD Filtration & Drying trail conducted to reduce the drying time cycle in Atorvastatin Calcium (ATSC3), slow filtration and hard lumps observed.
- RCVD trail for Atorvastatin Calcium (ATSC3) for drying to be plan.
- Homogenizer trails planning for Atorvastatin Calcium.
- Oseltamavir Phosphate with additional facility & Scale – up in C-Block proposed for EEPC2 Stage.
- Pantoprazole sodium Equipment mapping for 180 Kg batch size in A-Block facility to be execute.

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